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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/782,015	02/12/2001	Edmund Y.M. Chein	00115P002D	2156

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EXAMINER

GUPTA, ANISH

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 12/17/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/782,015

Applicant(s)

CHEIN, EDMUND Y.M.

Examiner

Anish Gupta

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM  
THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 11 October 2002.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 10-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 10-17 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:  
1. Certified copies of the priority documents have been received.  
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) Notice of References Cited (PTO-892)                    4) Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.  
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)                    5) Notice of Informal Patent Application (PTO-152)  
3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.                    6) Other:

**DETAILED ACTION**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9-23-02 has been entered.

2. The amendment filed 10-11-02 is acknowledged. Claims 10 and 14 were amended. Claims 10-17 are pending in this application.

3. All rejections made in the previous office action and not cited herein are hereby withdrawn in view of Applicants amendment.

*Claim Rejections - 35 USC § 103*

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 10-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Danielov et al. (US5885974).

Applicants assert that the reference does not teach the required element or the required amount of independent claim 10 or 14. "Specifically, Danielov does not teach or provide any motivation for a kit containing an effect and administrable amount of HGH and at least one supplemental hormone to establish a regimen of replenishment of the hormones within a body to physiological levels."

Applicant's arguments filed 10-11-02 have been fully considered but they are not persuasive.

The specification states that the HGH is administered less than .5mg per day (see page 14, lines 1-5). The reference teaches the administration of HGH in 1-10 micrograms. This concentration is well within the concentration range for HGH disclosed in the specification. Further, the reference repeatedly states that the kit can be used in parenteral form for the treatment of trauma or shock (see col. 5, lines 15-17). Further, the reference teach that the composition results "in the resumption of normal cell metabolism" and has concentration that are within the claimed range (see claim 4). Thus, the composition, since it is given parenterally and in the claimed concentration range, the physiological concentration would necessarily be achieved. Applicants have not distinguished a kit in any other way, other than concentration. Thus, the reference renders obvious the claimed invention.

Rejection is maintained.

### *Double Patenting*

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 10-17 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 26-34 of U.S. Patent No. 5,855,920. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the reasons set forth in the previous office action and the reasons set forth below.

Applicants traverse the rejection and state that a terminal disclaimer disclaim portion of the term of any patent will be considered once the claims are otherwise in condition for allowance.

7. Applicant's arguments filed 10-11-02 have been fully considered.

Till a terminal disclaimer disclaiming the terminal portion of any patent granted on this application has been filed, the rejection will be maintained.

### New Ground for Rejections

### *Claim Rejections - 35 USC § 112*

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 10-17 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the reasons set forth in the previous office action and the reasons set forth below.

Claim 10 and 14 seem to be incomplete. Both claim states "replenishment of the human growth hormone and the at least." It seems that after growth hormone and the, something else should be present.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (703) 308-4001. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback , can normally be reached on (703)306-3220. The fax phone number of this group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Anish Gupta

*Brenda Brumback*  
BRENDA BRUMBACK  
SUPERVISORY PATENT EXAMINER  
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